

Amendments to the Specification

Please amend the specification of International Publication Number WO/ 2005/016170 as follows:

On page 2, please replace paragraph 1 that starts with the words “It is the object” and ends with the words “of the claims.” with the following amended paragraph:

It is the object underlying the present invention to provide an improved unit-dose syringe for multi-component material comprising a minimum number of easy-to-manufacturing parts, which are easy to manufacture. ~~This object is achieved with the features of the claims.~~

On page 2, please replace paragraph 2 that starts with the words “In order to achieve” and ends with the words “part of the syringe.” with the following amended paragraph:

~~In order to achieve the above object, the~~The present invention provides a unit-dose syringe providing an integrated and preferably self-opening closure to encapsulate material, preferably dental material, and to keep the compartments of the material separate during storage. The self-opening closure is easily openable for mixing and application of the material by moving preferably only one part of the syringe.

On page 2, please replace paragraph 4 that starts with the words “According to a first” and ends with the words “of said cartridge.” with the following amended paragraph:

According to a first aspect of the present invention, there is provided a unit-dose syringe for a multi-component ~~material~~ material, comprising a cartridge having a first end and a second end, and having a compartment for each component, a static mixer connectable with said cartridge at its first end, a mixing tip being integrally connected to the cartridge at said first end of said cartridge and receiving said static mixer, and a plunger for dispensing material from said cartridge through said mixing tip, said plunger being arranged at said second end of said cartridge.

On page 2, please replace paragraph 5 that starts with the words “The static mixer” and ends with the words “by the present invention.” with the following amended paragraph:

The static mixer preferably comprises closure plugs at ~~is~~ the rear end for closing the outlet openings of the compartments of the cartridge. Furthermore, the static mixer preferably comprises a mixing helix, and an outlet tip at the front end of the mixing helix. According to a preferred embodiment, the outlet tip is connected to the mixing helix by ~~means of~~ a hinge. A collapsible static mixer ~~being collapsible~~ is also encompassed by the present invention.

On page 3, please replace paragraph 1 that starts with the words “It is furthermore preferred” and ends with the words “of the mixing tip.” with the following amended paragraph:

It is furthermore preferred that the outlet tip of the static mixer is accommodated within the mixing tip during storage of the syringe. In this case, the front end of the mixing tip and the outlet tip of the static mixer comprise corresponding ~~retention means~~ retainers that allow the outlet tip to project beyond the front end of the mixing tip upon activation of the ~~syringe~~ syringe, but prevent that the outlet tip completely extends beyond the mixing tip. The ~~retention means~~ retainer at the front end of the mixing tip preferably comprises a recess in the wall of the mixing tip, and the ~~retention means~~ retainer of the outlet tip comprises a projection at the circumference of the rear end of the outlet tip, wherein the projection is engagable by the recess once the syringe is activated and the outlet tip is moved outwards of the mixing tip.

On page 3, please replace paragraph 2 that starts with the words “According to a further” and ends with the words “by this embodiment.” with the following amended paragraph:

According to a further preferred embodiment, the mixing tip is connected to the cartridge by ~~means of~~ a hinge. This is advantageous because a fold-away mixing tip provides the option to mold the outlet tip integral with the mixing tip rather than with the mixer. As the mixing tip is tapered to the outlet end molding is only possible if the core can be removed from the back end of the mixing tip which is facilitated by this embodiment.

On page 3, please replace paragraph 3 that starts with the words “In an alternate” and ends with the words “tip for mixing.” with the following amended paragraph:

In an alternate embodiment of the first aspect of the present invention, the mixing tip forms an extension of a first ~~of the compartments~~ compartment of the cartridge. In this case, the mixing tip comprises the outlet tip at its front end. Furthermore, the first and a second compartments are connected by a passageway ~~being~~ provided adjacent the first end of the cartridge. The second compartment comprises a plug sealing the second compartment against that opening of the passageway facing towards the interior of the second compartment. The static mixer comprises at its rear end a plug sealing the first compartment against that opening of the passageway facing towards the interior of the first compartment. Thus, activation of the syringe by the plunger moves the two plugs along the longitudinal direction of the syringe in order to free the passageway so that material is allowed to flow from the two compartments into the mixing tip for mixing.

On page 4, please replace paragraph 1 that starts with the words “According to the second” and ends with the words “into the mixing tip.” with the following amended paragraph:

According to the second aspect of the present invention, the cartridge preferably comprises a recess at its first end extending in the longitudinal direction for receiving the rear end of the mixing tip. The cartridge comprises radial openings in the wall of the recess for providing passageways from the compartments to the recess. Furthermore, the mixing tip comprises radial openings that correspond to and align with the radial openings in the recess wall to provide passageways from the compartments into the mixing tip.

On page 4, please replace paragraph 2 that starts with the words “Preferably, the static” and ends with the words “of the passageway openings.” with the following amended paragraph:

Preferably, the static mixer comprises a mixing helix. Furthermore, the static mixer comprises a spacer at the rear end of the mixing helix. The spacer extends along the longitudinal axis of the static mixer. The said static mixer also comprises a closure element at the rear end of the spacer.

The spacer extends in the longitudinal direction along the width of the passageways at the rear end of the mixing tip such that the closure element is located rearwards of the passageway openings.

On page 4, please replace paragraph 5 that starts with the words “It is furthermore” and ends on page 5 with the words “direction of the syringe.” with the following amended paragraph:

It is furthermore preferred according to a first alternative of the third aspect of the present invention that the mixing tip comprises an axially acting rotary slide valve at its end that is connectable to the first end of the cartridge. The axially acting rotary slide valve preferably comprises passageways and seal areas that are alternately alignable with the outlet openings of the cartridge compartments. More preferably, the valve also comprises a locking mechanism that is engageable with a corresponding locking mechanism at the first end of the cartridge. The locking mechanism at the cartridge comprises pins that are engageable in corresponding recesses forming the locking mechanism of the valve. Preferably, the pins and said recesses are formed such that a thread lock is obtained interlocking the mixing tip and the cartridge in the longitudinal direction of the syringe.

On page 5, please replace paragraph 1 that starts with the words “According to a second” and ends with the words “low viscous materials.” with the following amended paragraph:

According to a second alternative of the third aspect of the present invention, the outlet openings of the compartments are directed transverse to the longitudinal axis of the syringe. In this case, the mixing tip comprises a radially acting rotary slide valve at its end that is connectable to the first end of the cartridge. The radially acting rotary slide valve preferably comprises a body member forming a cavity that corresponds to the outer surface of the cartridge in the area of its ~~first~~ first end for receiving the first end of the cartridge. The wall of the cavity comprises recesses along the longitudinal axis of the body member, and the recesses are alignable with the outlet openings of the cartridge for forming passageways from the compartments of the cartridge to the static mixer. The use of a radially acting rotary valve in combination with transversely directed

outlet openings is advantageous for optimum sealing of the cartridge especially for low ~~viscous~~ viscosity materials.

On page 5, please replace paragraph 2 that starts with the words “According to a preferred” and ends with the words “circumferential outer surface.” with the following amended paragraph:

According to a preferred embodiment of all aspects of the present invention, the cartridge comprises at its outer surface extensions or protrusions ~~being sized and shaped~~ to provide the cartridge with a substantially circular circumferential outer surface.

On page 5, please replace paragraph 4 that starts with the words “It is also preferred” and ends with the words “of said cartridge.” with the following amended paragraph:

It is also preferred in all aspects of the present invention that the plunger comprises a separate piston for each compartment of said cartridge.

On page 5, please replace paragraph 6 that starts with the words “According to a fourth” and ends on page 6 with the words “a static mixer.” with the following amended paragraph:

According to a fourth aspect of the present invention, a unit-dose syringe for a multi-component material is provided that comprises a cartridge having a first end and a second end, and ~~having~~ has a compartment for each component. The compartments extend between said first end and said second end. A plunger for dispensing material from the cartridge is arranged at a second end of the cartridge. Furthermore, a mixing tip is connectable to the cartridge at the first end of the cartridge ~~and for~~ receiving a static mixer.

On page 9, please replace paragraph 1 that starts with the words “The plunger 103” and ends with the words “the rear end.” with the following amended paragraph:

The plunger 103 which is shown in more detail in Fig. 3 comprises two pistons, 109, 110 which are integrally connected with each other at the rear end 111 of the plunger 103. The ~~to~~ two pistons 109, 110 engage in each of the two compartments or barrels 105, 106 of the cartridge 101, in order to dispense the components contained in the compartments 105, 106. In the inactivated state of the syringe, the pistons 109, 110 close the barrels 105, 106 of the cartridge on a first end, i.e., the rear end.

On page 9, please replace paragraph 3 that starts with the words “The syringe 100” and ends with the words “step in diameter.” with the following amended paragraph:

The syringe 100 according to the first aspect of the present invention is activated by moving the plunger 103 with its pistons at its front end into the cartridge 101. This causes the plugs 113 formed at the static mixer 112 to be pushed out of the front outlet openings of the compartments of the cartridge 101 due to hydraulic pressure of the dental material (paste). The mixing helix 114 is thus enabled to be moved along the longitudinal axis of the mixing tip 102 within a distance defined by the contractibility/elasticity of the mixing helix 114. Alternatively the mixing helix 114 can move towards the outlet of the mixing tip 102 over a defined distance. The distance the mixing helix 114 can move may be limited by a retension mechanism 118, 119 inside of the mixing tip 102, e. g. a step (reduction) in diameter.

On page 10, please replace paragraph 1 that starts with the words “In addition to illustrating” and ends with the words “outlet tip 115.” with the following amended paragraph:

In addition to illustrating the general operation of the syringe 100, Fig. 6 shows further preferred features. First, according to the preferred embodiment of Fig. 6, the outlet tip 115 does not project beyond the outlet opening of the mixing tip 102 in the inactivated state of the syringe 100 but is accommodated within the mixing tip 102. Only upon activation of the syringe 100, the outlet tip 115 is pushed out of the front opening of the mixing tip 102 and then projects beyond the mixing tip 102. Secondly, a further preferred feature is the provision of a retention mechanism 118, 119. Such a retention mechanism 118, 119 is preferred for front-assembled syringes. The retention mechanism is provided at the opening of the mixing tip (118) as well as

at the rear end of the outlet tip 115 (119). Thus, forward movement of the outlet tip 115 is stopped by the retention mechanism which at the same time forms a seal between the outer surface of the outlet tip 115 and the inner surface of the mixing tip 102 thus ensuring that the mixed paste ~~flowing~~ flows through the outlet tip 115.

On page 10, please replace paragraph 2 that starts with the words “Such retention mechanism” and ends with the words “mixing tip 102.” with the following amended paragraph:

~~Such~~ One such retention mechanism is shown in greater detail in Fig. 9. In the upper drawing of Fig. 9, the outlet tip 115 already slightly projects beyond the mixing tip 102, whereas in the lower drawing the outlet tip 115 is in its fully projected position. The part ~~418~~ 119 of the retention mechanism provided at the outlet tip 115 is in the form of a projecting flange, whereas the part 118 of the retention mechanism provided at the mixing tip 102 is in the form of a recess. Once the flange 119 has reached the recess, it springs out into the recess and prevents further movement of the static mixer 112. At the same time, a seal 120 is formed between the outlet tip 115 and the mixing tip 102.

On page 11, please replace paragraph 3 that starts with the words “The syringe assembly” and ends with the words “at its rear end.” with the following amended paragraph:

The syringe assembly 200 of Fig. 11 comprises a cartridge 201 and a separate mixing tip/mixing barrel 202. The front ~~opening-s~~ openings of the two compartments of the cartridge 201 are closed with foil-type closures 203 which improves the storage stability properties. The foil-type closure 203 is preferably made as a peel closure. Alternatively, the foil-type closure is punchable. This option is illustrated in Fig. 11. The mixing barrel 202 comprises interconnecting sockets 204 or 205 with punching elements at its rear end, as shown in Figure 11a.

On page 11, please replace paragraph 6 that starts with the words “Fig. 12 shows a” and ends with the words “are arranged concentrically.” with the following amended paragraph:

Fig. 12 shows a further alternative embodiment. Syringe 300 comprises a cartridge ~~302~~ 301 which has an outer round shape, preferably cylindrical, and at least one inner separation wall 307 separating two compartments 305, 306 from each other. A plunger 303 is accordingly adapted and particularly comprises a longitudinal slot 308 for receiving the separation wall 307 during use of the syringe 300. As an alternative option (not shown), the compartments are arranged concentrically.

On page 11, please replace paragraph 7 that starts with the words “A further preferred syringe” and ends on page 12 with the words “from the passageway 431.” with the following amended paragraph:

A further preferred syringe 400 is shown in Figs. 13 to 15. In this embodiment, syringe 400 comprises a cartridge 401 being formed of an elongated main barrel 405 and one ~~ore~~ or more side barrels 406. The main barrel 405 also forms the mixing barrel ~~402~~ 403, preferably comprising an intra-oral outlet tip 415. As an alternative option, the barrels are arranged concentrically (not shown). Within the mixing barrel ~~402~~ 403, a mixing helix 414 is provided. Rear plug 413 closes the front end of the main barrel 405. At the front end of the side barrel 406, a piston 430 is provided that closes a passageway 431 connecting the main with the side barrels. In the inactivated state of the syringe 400, plug 413 closes the main barrel 405 such that the material contained in ~~he~~ the main barrel 405 cannot reach the passageway 431, i.e., plug 413 separates the material in main barrel 405 from the passageway 431.

On page 12, please replace paragraph 1 that starts with the words “For activation of the syringe” and ends with the words “illustrated in Fig. 14.” with the following amended paragraph:

For activation of the syringe, a dual plunger (not shown) is moved into the syringe 400. This causes the piston 430 within the side barrel 406 and at the same time the mixing helix 414 with its plug 413 to move forward and to open the passageway 431, which allows the material in the two compartments 405, 406 to flow through the passageway 431 into the mixing barrel ~~402~~ 403. This is illustrated in Fig. 14.

On page 12, please replace paragraph 2 that starts with the words “In a preferred embodiment” and ends with the words “outlet tip 504.” with the following amended paragraph:

In a preferred embodiment, as shown in Fig. 15, a collapsible mixing helix 512 is used. In this case, the arrangement and structure of the pistons 509 and 510 and plungers is different to the previously described embodiments. In this embodiment, two plungers 503₁ and 503₂ are provided. One of these two plungers is shorter (plunger 503₁) than the other. The longer plunger 503₂ comprises a projection 540 that interacts with the other plunger 503₁ such that movement of the shorter plunger in longitudinal direction, i.e. into the cartridge 501 also causes movement of the other, longer plunger. Projection 540 functions as a catch. ~~A-~~ As shown in the drawing in the middle of Fig. 15, after activation of the syringe 500, the two pistons have reached the front end of the cartridge 501 and have pressed the components of the material to be mixed into and through the collapsible mixing ~~helix.~~ helix 512. In order to also remove and use the material that remains in the mixing tip 502, the longer plunger 503₂ is pushable further until it ~~even~~ reaches the outlet tip 504. This is illustrated in the bottom drawing of Fig. 15. In this state, i.e., after application, the mixing helix is substantially completely collapsed within the outlet tip 504.

On page 13, please replace paragraph 2 that starts with the words “This construction is advantageous” and ends with the words “material applicator pistons.” with the following amended paragraph:

This construction is advantageous if the required diameter for the mixing helix 614 is much smaller than the diameter (or cross-section) of the smallest material barrel because the remaining material within the mixing barrel can thus be reduced to a minimum. This construction is also usable with a collapsible mixer 614. ~~in~~ In this case a separate piston for compressing the mixer would be used. This piston - placed within the rear end of the mixing barrel – would be movable independently from the material applicator pistons.

On page 14, please replace paragraph 1 that starts with the words “According to another” and ends with the words “of the mixing tip.” with the following amended paragraph:

According to another aspect of the present invention, and as shown in Fig. 20, cartridge 701 of syringe 700 comprises a recess 750 at its front end, e.g., a cylindrical bore, for receiving an exchangeable mixing tip/mixing barrel. The recess 750 comprises lateral passageways 751 into the material barrels 705, 706. The exchangeable mixing barrel also comprises passageways which can be aligned to the passageways 751 in the recess 750 thus forming a passageway from the material barrels to the inside of the mixing tip.

On page 14, please replace paragraph 3 that starts with the words “This aspect of the” and ends with the words “the material flow.” with the following amended paragraph:

This aspect of the present invention is advantageous because no forces occur in the longitudinal direction between the cartridge and the mixing tip resulting from the material flow through lateral passageways. Even forces in the longitudinal direction between the mixing tip 702 and the mixing helix 714 are eliminated as the closure plug 713 of the helix compensates for the forces resulting from the material flow.

On page 14, please replace paragraph 4 that starts with the words “An additional advantage” and ends with the words “cartridge is reduced.” with the following amended paragraph:

An additional advantage is that the connecting system used in this aspect can be used as a valve and provides the possibility to use the syringe as multi-dose system. In this case, the mixing barrel is rotated within the recess until the passageways in the mixing tip and the passageways in the recess, respectively, are unaligned, thus closing the cartridge. A separate cap for closing the cartridge during storage is therefore not necessary. ~~Further to saving the cap the~~ The risk of using a wrong mixer with the material filled in the cartridge is reduced.

On page 14, please replace paragraph 5 that starts with the words “The option of having” and ends on page 15 with the words “drawing of Fig. 23.” with the following amended paragraph:

The option of having a self-opening valve at the front end of the cartridge is described in more detail with regard to Fig. 23. Fig. 23 shows in its left drawing a plug 10, preferably cylindrical, that comprises a concentric lip 11 projecting along a substantial part of the length of the plug so that a concentric U-shaped recess 12 is formed. Upon application of pressure, as shown in the middle drawing of Fig. 23, the flexible lip is ~~deformed~~, deformed, and subsequently pushed backwards so that a passageway into the mixing tip (not shown) is opened (see arrows in the right drawing of Fig. 23).

On page 15, please replace paragraph 4 that starts with the words “A preferred opening” and ends with the words “tip (not shown).” with the following amended paragraph:

A preferred opening mechanism for a powder/liquid syringe 800 is shown in Fig. 25. For ease of explanation, Fig. 25 merely shows a partial cross-sectional view of the two ~~barrel~~ barrels of the cartridge, i.e., the barrel 805 for the powder, and the barrel 806 for the liquid. The arrangement as shown in Fig. 25 provides a double function rotary slide valve. In the inactivated position as shown in the left drawing of Fig. 25, the two barrels 805, 806 are separated from each other by the surrounding walls 874 and 875. Inclined channels 872, 873 are provided in the walls, which are unaligned in the inactivated state. In this embodiment, the two barrels are rotatable relative to each other, as indicated by the top arrow in the right drawing of Fig. 25. For activation, the inner barrel 806 with its wall 875 is rotated by 180° until the inclined channel 873 provided in wall 875 is aligned with the other inclined channel 872 provided in wall 874. The liquid flows through the resulting inclined ~~channel~~ channel. At the same time, the front opening 871 is opened thus allowing the liquid/powder mixture to flow out, and into the mixing tip (not shown).

On page 17, please replace paragraph 1 that starts with the words “A further optional feature” and ends with the words “of the cartridge 901.” with the following amended paragraph:

A further optional feature is shown in Figs. 31 and 37. In these embodiments, the outer surface of the cartridge is provided with a grip support facilitating the syringe to be held in any angle of rotation by the dentist. This feature is particularly preferred if the cartridge does not have a circular cross-sectional shape such as a twin barrel cartridge. In Fig. 31, the grip support is

formed by two flanges projecting along the longitudinal axis of the cartridge from the rear end of the cartridge towards its front end thus providing a feeling to the dentist of having a cartridge with a circular cross-section in the hands. According to Fig. 37, the grip support is provided by a plurality of ribs or fins extending at the outer surface of the cartridge from the rear end of the cartridge a certain length along the longitudinal axis of the cartridge. The ribs have different heights in order to provide said feeling of holding a circular cartridge. In Fig. 37, the longest rib 990 has a larger height than the shorter ribs, the height decreasing from the longest rib to the shortest rib because the longest rib 990 is provided just in the groove between the two barrels of the cartridge 901.

On page 17, please replace paragraph 2 that starts with the words “A further preferred embodiment” and ends with the words “cartridge during storage.” with the following amended paragraph:

A further preferred embodiment of this aspect especially suitable for low ~~viscous~~ viscosity materials is now described with reference to Figs. 32 to 36. The main difference to the embodiment shown, e.g., in Fig. 26 is the use of radially acting rotary slide valve 995 instead of an axially acting rotary slide valve. For low ~~viscous~~ viscosity materials, a radially acting rotary slide valve is advantageous with regard to sealing of the cartridge during storage.

On page 17, please replace paragraph 3 that starts with the words “In the embodiment” and ends on page 18 with the words “by the arrows.” with the following amended paragraph:

In the embodiment shown in Fig. 33 which is a cross-sectional view of syringe 900 with radially acting rotary slide valve 995, cartridge outlets 996 are arranged in a direction transverse to the axis of the syringe 900 thus providing the possibility of radially sealing the outlet bores of the syringe. As a result, a change of the flow direction of the materials will occur during application. The radial arrangement of the valve is advantageous for optimum sealing of the cartridge which is especially required for low ~~viscous~~ viscosity materials. Opening and closing of the syringe 900 is made by rotating the mixing tip 902 by a predetermined angle. In the opened position, longitudinally arranged grooves within the coupling part of the mixing tip 902 are aligned with

the radial outlet bores 996 in the cartridge 901 thus forming a passageway for the material components to flow into the mixing tip 902, as indicated in Fig. 33 by the arrows.